We claim:

1. A fluid-imbibing device for delivering an active agent to a fluid environment of use, said device comprising a water-swellable semipermeable material that is received in sealing relationship with the interior surface of one end of an impermeable reservoir and an active agent to be displaced from the device when the water-swellable material swells.

2. The device of claim 1 wherein the semipermeable material is selected from the group consisting of plasticized cellulosic materials, polyurethanes and polyamides.

3. The device of claim 1 wherein the aspect ratio of the plug is 1:10 to 10:1 length to diameter.

4. The device of claim 1 wherein the semipermeable material is assembled into an open end of the reservoir.

5. The device of claim 1 wherein the semipermeable material is assembled into a cavity in said reservoir.

6. The device of claim 5 wherein the cavity is of a shape selected from the group consisting of a cylindrical, stepped, helical threaded and spaced configuration.

7. The device of claim 1 wherein the active agent is selected from the group consisting of a protein, a peptide or a gene therapy agent.

8. The device of claim 7 wherein the active agent is an LHRH agonist or antagonist.

9. The device of claim 7 wherein the active agent is leuprolide.

10. The device of claim 7 wherein the active agent is selected from the group consisting of Factor VIII and Factor IX.

11. The device of claim 1 wherein the active agent is delivered to a site remote from the device.

12. An implantable device for delivering an active agent to a fluid environment of use, said device comprising a reservoir and a back-diffusion regulating outlet in mating relationship, wherein a flow path for the active agent comprises a pathway formed between the mating surfaces of the reservoir and the back-diffusion regulating outlet.

13. The device of claim 12 where the active agent is delivered at a rate of 0.02 to 50 μl/day.

14. The device of claim 12 wherein the active agent is selected from the group consisting of a protein, a peptide or a gene therapy agent.

15. The device of claim 14 wherein the active agent is leuprolide.

16. The device of claim 12 wherein the active agent is delivered to a site remote from the device.

17. A device for storing an active agent in a fluid environment of use during a predetermined administration period, the device comprising a reservoir containing an active agent, said reservoir being formed at least in part from a metallic material, the portion of said reservoir contacting said active agent being non-reactive with the active agent, said metallic material in

contact with active agent being formed of a material selected from the group consisting of titanium and its alloys.

18. The device of claim 17 wherein the titanium alloy is at least 60% titanium.

19. The device of claim 17 wherein the active agent is selected from the group consisting of a protein, a peptide or a gene therapy agent.

20. The device of claim 19 wherein the active agent is delivered to a site remote from the device.

21. An implantable fluid-imbibing active agent delivery system comprising an impermeable reservoir and containing a piston that divides the reservoir into an active agent containing chamber and a water-swellable agent containing chamber, wherein the active agent containing chamber is provided with a back-diffusion regulating outlet and the water-swellable agent containing chamber is provided with a semipermeable plug; wherein the plug is releasable from the reservoir at an internal pressure that is lower than the maximum osmotic pressure generated by the water-swellable agent.

22. An implantable fluid-imbibing active agent delivery system comprising an impermeable reservoir and containing a piston that divides the reservoir into an active agent containing chamber and a water-swellable agent containing chamber, wherein the active agent containing chamber is provided with a back-diffusion regulating outlet and the water-swellable agent containing chamber is provided with a semipermeable plug; wherein the outlet is releasable from the reservoir at an internal pressure that is lower than the maximum osmotic pressure generated by the water-swellable agent.

23. A fluid-imbibing implantable active agent delivery system for delivering an active agent to a fluid environment of use for a predetermined administration period, wherein the time to start-up is less than 10% of the predetermined administration period.

24. A method for preparing a fluid-imbibing implantable active agent delivery system for delivering an active agent to a fluid environment of use for a predetermined administration period said method comprising injection molding a semipermeable plug into the end of an impermeable reservoir such that the semipermeable plug is protected by the reservoir.

25. The method of claim 24 wherein the semipermeable plug material is a polyurethane based material.

26. The method of claim 24 wherein the semipermeable plug material is a polyamide based material.

27. The method of claim 24 wherein the semipermeable plug material is a cellulosic based material.

28. An implantable active agent delivery system for delivering an active agent to a fluid environment of use, said agent being susceptible to degradation if exposed to the fluid environment of use prior to delivery, said system comprising:

(a) a piston that divides the system into a first and second chamber, the first and second chambers each having an open end;

(b) a water-swellable agent formulation in the first chamber;

(c) an active agent formulation in the second chamber;

(d) a semipermeable plug in the open end of the first chamber; and

(e) a back-diffusion regulating outlet in the open end of the second chamber;

wherein said system effectively seals the active agent chamber and isolates it from the environment of use.

29. The system of claim 28 wherein the active agent is selected from the group consisting of a protein, a peptide or a gene therapy agent.

30. The system of claim 28 wherein the active agent is leuprolide.

31. A back-diffusion regulating outlet useful in an active agent delivery system for delivering active agent to a fluid environment of use, said outlet defining a flow path wherein the length, interior cross-sectional shape and area provide for an average linear velocity of the active agent that is higher than the linear inward flux of the fluid environment of use.

32. The outlet of claim 31 wherein the flow path is helical in shape.

33. A semipermeable plug useful in an active agent delivery system for delivering an active agent to a fluid environment of use, said plug being water-swellable and expanding linearly in said delivery system to commence pumping of active agent upon insertion of the delivery system in the fluid environment of use.

34. An implantable leuprolide delivery system comprising:

(a) an impermeable reservoir;

(b) a piston that divides the reservoir into a first and a second chamber, the first and second chambers each having an open end;

(c) a water-swellable agent formulation in the first chamber;

(d) a leuprolide formulation in the second chamber;

(e) a semipermeable plug in the open end of the first chamber; and

(f) a back-diffusion regulating outlet in the open end of the second chamber;

wherein the system effectively seals the second chamber and isolates the leuprolide formulation from the environment of use.

35. The system of claim 34 wherein the reservoir is titanium or a titanium alloy.

36. The system of claim 34 wherein the piston is formed of C-Flex® TPE.

37. The system of claim 34 wherein the water-swellable agent formulation contains at least about 64 mg NaCl.

38. The system of claim 34 wherein the water-swellable agent formulation contains NaCl, a gelling osmopolymer and granulation and processing aids.

39. The system of claim 34 further comprising an additive in the first chamber.

40. The system of claim 39 wherein the additive is PEG 400.

41. The system of claim 34 wherein the leuprolide formulation is leuprolide acetate dissolved in DMSO at an assayed content of 37% leuprolide.

42. The system of claim 34 which contains 65 mg leuprolide.

43. The system of claim 34 wherein the semipermeable plug is formed of polyurethane material with 20% water uptake.

44. The system of claim 34 wherein the back-diffusion regulating outlet is made of polyethylene and has a flow path helical in shape with a diameter between 0.003 and 0.020 inches and a length of 2 to 7 cm.

45. The system of claim 34 which delivers about 0.35 μL leuprolide formulation per day.

46. The system of claim 45 which provides continuous delivery of leuprolide formulation for about one year.

47. The system of claim 34 which reaches at least about 70% steady-state delivery by day 14.

48. The system of claim 34 which delivers about 150 μg leuprolide per day.

49. A method of treating a subject suffering from prostatic cancer comprising administering at least one system of claim 34.

50. An implantable leuprolide delivery system comprising:

(a) a titanium alloy reservoir;

(b) a C-Flex® TPE piston that divides the reservoirs into a first and a second chamber, the first and second chambers each having an open end;

(c) a compressed NaCl-based osmotic engine and a PEG additive in the first chamber;

(d) 65 mg leuprolide as a leuprolide acetate solution in DMSO in the second chamber;

(e) a semipermeable polyurethane plug with 20% water uptake in the open end of the first chamber; and

(f) a polyethylene back diffusion regulating outlet with a helical flow path in the open end of the second chamber;

wherein the system continuously delivers about 150 μg leuprolide per day for about one year after subcutaneous implantation.